REMARKS

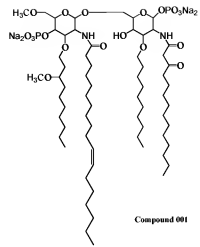
Claims 120-123, 125-128, 130-133 and 135-138 were pending. Claims 127 and 137 have been canceled without prejudice. Accordingly, after entry of the present amendment, claims 120-123, 125-126, 128, 130-133, 135-136 and 138 will remain pending. *No new matter has been added.* Applicant reserves the right to pursue canceled or amended subject matter in one or more continuing or divisional applications.

Only one ground for rejection, the rejection under 35 U.S.C. §103(a), presently remains. As a preliminary matter, Applicant would like to thank Examiners Olson and Jiang for their time during the Examiner's Interview held on April 29, 2008, during which the remaining ground for rejection was discussed.

Claim Rejections – 35 U.S.C. 103

Claims 120-123, 125-128, 130-133 and 135-138 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rossignol *et al.* (U.S. Patent No. 6,184,366). Specifically, the Office Action, at page 7, states that it "the '366 patent discloses a genus of compounds… the synthesis of a substantial number of which would require the use of different protecting groups for the several hydroxyl groups of the sugar moiety. Such need would have given one of ordinary skill in the art reason to pursue multiple protecting groups for and their deprotection to synthesize" the final product. The Office Action also states, at page 8, that "if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species…"

Applicant respectfully traverses the rejection. The '366 patent discloses a method of making disaccharide compounds, *e.g.*, Compound (001):



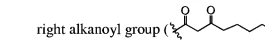
Compound 001

The claims of the present application are directed to intermediates used in a new and improved process of making Compound (001). Applicant respectfully submits that the '366 patent does not teach or suggest the intermediates of the present invention, nor does the '366 patent suggest methods for making or using such intermediates.

Submitted herewith is a Declaration Under 37 CFR §1.132, by Dr. James E. Foy ("Foy Declaration"). The Foy Declaration provides evidence that the present claimed intermediates would not have been obvious to one of ordinary skill in the art, in view of the '366 patent. In the Declaration, Dr. Foy states that the present claimed compounds can be used as intermediates in making the "left saccharide" portion and the "right saccharide" portion of compounds of formula (001), shown above. Specifically, the compositions of the invention "make it possible to synthesize the right [and left] saccharide… in significantly fewer steps" and avoid protection and deprotection steps disclosed in the '366 patent, and thus "reduce[d] the number and quantity of reagents needed and increased the overall yield." (see Foy Declaration, paragraphs 9 and 11).

The '366 patent discloses a process for synthesizing the "left saccharide" whereby the amino substituent is protected by a Troc moiety (*i.e.*, ) and a left alkanoyl group () is added ***after the introduction of a phosphate group and after the coupling of the right saccharide to the left saccharide***. As indicated in the Foy Declaration, "[t]he present invention provides new and unobvious intermediates which are prepared using new and unobvious methods for synthesizing the ***left saccharide*** where the left alkanoyl group is added early in the synthesis, prior to the introduction of the phosphate group

and prior to the coupling with the right saccharide." (emphasis added; see Foy Declaration, paragraph 9). Such intermediates are reflected in pending claims 120-123 and 130-133.

Similarly, the '366 patent discloses a process for synthesizing the "right saccharide" whereby the amino substituent is protected by a diphenylimine moiety (*i.e.*, ) and a right alkanoyl group () is added ***after the introduction of an allyl ester group***. As indicated in the Foy Declaration, "[t]he present invention provides new and unobvious intermediates which are prepared using new and unobvious methods for synthesizing the ***right saccharide*** where the right alkanoyl group is added early in the synthesis, prior to the introduction of the allyl carbonate group." (emphasis added; see Foy Declaration, paragraph 11). Such intermediates are reflected in pending claims 125-126, 128, 135-136 and 138.

Applicants respectfully submit that a person of ordinary skill in the art would not have been motivated to make the compounds of the present invention. As noted by Dr. Foy in paragraph 6 of the Foy Declaration, with regard to the improved intermediates presented herein, "[i]t was unexpected at the time the claimed invention was made that this improvement would lead to a feasible process. For example, when this improvement was suggested to the Process Research department by the inventor… the general belief within the department was that such an improved process would not be possible…" More specifically, as noted in the Foy Declaration, "a person of ordinary skill in the art would have found it unexpected that that the alkanoyl groups could act as protecting groups, and that the compounds protected with alkanoyl groups would be suitable as intermediates in the processes described herein. This belief was based, at least in part, on the potential reactivity of the alkanoyl-protected intermediates with reagents utilized in the synthesis of the disaccharide compound shown in paragraph 7 (*e.g.*, phosgene, Oxone®, etc.), as discussed in more detail herein." (see Foy Declaration, paragraph 12).

With regard to the "left saccharide," the synthesis of the final product requires reagents (*e.g.*, Oxone®) which not only react with the amine groups of the unprotected sugar, but also react with alkenes such as the alkene introduced into the left saccharide when the left alkanoyl group is coupled to the left saccharide. Specifically, as noted in paragraph 14 of the Foy Declaration, Oxone® "can oxidize amine nitrogens to nitrosoalkanes and/or oximes" and "may also react with an alkene to form an epoxide, as disclosed in Bloch, R. *et al.*, *J Org. Chem.*

50:1544-45 (1985)..." In view of this, Applicant respectfully submits that a person of ordinary skill in the art would have no reasonable expectation, based upon the teachings of the '366 patent, that an amine group of the left saccharide would be suitably protected with the left alkanoyl group as in the intermediates of the presently claimed invention. Accordingly, as indicated by Dr. Foy in paragraph 14 of the Foy Declaration, "there would have been no reason for a person of ordinary skill in the art to modify the left saccharide compounds of U.S. 6,184,366 in the particular manner described in the present methods..." at least because "one of ordinary skill in the art could not have predicted that Oxone® would not attack the alkene introduced into the intermediate upon coupling of the left alkanoyl group and the left saccharide."

With regard to the "right saccharide," the synthesis of the final product requires reagents (*e.g.*, phosgene) which not only react with the amine groups of the unprotected sugar, but also react with amide groups such as the amide group formed when the right alkanoyl group is coupled to the right saccharide. Specifically, as noted in paragraph 13 of the Foy Declaration, phosgene "is extremely reactive with amine nitrogens" and "may also react with an amide bond to form an imidochloride, as disclosed in U.S. Patent No. 3,282,923..." In view of this, Applicant respectfully submits that a person of ordinary skill in the art would have no reasonable expectation, based upon the teachings of the '366 patent, that an amine group of the right saccharide would be suitably protected with the right alkanoyl group as in the intermediates of the presently claimed invention. Accordingly, as indicated by Dr. Foy in paragraph 13 of the Foy Declaration, "there would have been no reason for a person of ordinary skill in the art to modify the right saccharide compounds of U.S. 6,184,366 in the particular manner described in the present methods..." at least because "one of ordinary skill in the art could not have predicted that phosgene would not attack the amide bond formed upon coupling of the right alkanoyl group and the right saccharide."

In view of the above, Applicant respectfully submits that, a person of ordinary skill in the art would have found it unexpected that the left and right alkanoyl groups would suitably protect the left and right saccharides in the presence of reagents such as Oxone® and phosgene. That is, as noted by Dr Foy, it was "unexpected that the synthesis of the disaccharide could successfully proceed through the route described in the present invention (*e.g.*, the route without a Troc or

diphenylimine intermediate)." (see Foy Declaration, paragraph 15). With regard to this last point, the Office Action, at page 9, citing *In re Hack*, has indicated that "it is well settled that 'intended use' of a composition or product will not further limit claims drawn to a composition or product, so long as the prior art discloses the ***same composition comprising the same ingredients*** in an effective amount, as the instantly claimed." (emphasis added). However, Applicant respectfully submits that (1) the "intended use" of the intermediates presented herein was itself unexpected and thus could not provide motivation to the skilled artisan prior to the filing of the present invention and (2) the '366 patent ***does not*** claim the same composition comprising the same ingredients as the instantly claimed.

In view of the above, Applicant respectfully submits that the present claims are patentable over the '366 patent and requests withdrawal of the rejection under 35 U.S.C. §103(a) and reconsideration of the claims.

CONCLUSION

In view of the above, Applicant believes the pending application is in condition for allowance. The Examiner is invited to contact the undersigned with questions or comments with regard to this application.

Dated: July 2, 2008

Respectfully submitted,

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